Examiner's Amendment

8. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

9. Authorization for this Examiner's amendment was given in a telephone interview with Mr. William I. Solomon on 9 December 2005.

In the Claims:

- Cancel Claims 1, 4, 21, and 81-98:
- Add new Claims 99-119 as follows:

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99. (New) A pharmaceutical preparation comprising a compound (I), which is obtained by reacting a peptide (II) having a free amino group, with a sugar (III) having reducing power and selected from group A, wherein said peptide is a pharmaceutical compound,

wherein group A consists of lactose, sialyllactose and compounds prepared by chemically binding a polymer from the group consisting of polyoxyethylene, polyglutamic acid and polyvinylpyrrolidone to a hydroxyl group other than the hydroxyl group formed from the reducing aldehyde group of lactose and sialyllactose,

wherein an amino group of said peptide (II) reacts with an aldehyde group in said sugar (III); and

wherein said compound (I) can release said peptide (II) having a free amino group in response to changes in pH.

100. (New) The preparation according to claim 99, wherein said peptide (II) is insulin.

101. (New) The preparation according to claim 99, wherein said peptide (II) is enkephalin.

102. (New) The preparation according to claim 99, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is combined with a pharmaceutical carrier, to obtain a peptide-carrier composition, and said peptide-carrier composition is reacted with said sugar (III) to give said preparation comprising said compound (I).

103 (New) The preparation according to claim 99, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

104. (New) The preparation according to claim 99, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

said peptide (II) and said sugar (III) are encapsulated in a pharmaceutical carrier, and said peptide (II) is reacted with said sugar (III) to give said compound

(I) in said pharmaceutical carrier.

105. (New) The preparation according to claim 99, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

106. (New) The preparation according to any one of claims 102-105, wherein said pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

107. (New) The preparation according to claim 99, wherein said group A consists of lactose and sialyllactose.

108. (New) The preparation according to any one of claims 102-105, wherein said group A consists of lactose and sialyllactose.

109. (New) The preparation according to claim 106, wherein said group A consists of lactose and sialyllactose.

110. (New) The preparation according to claim 100, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

insulin is combined with a pharmaceutical carrier, to obtain an insulin-carrier composition, and said insulin-carrier composition is reacted with said

sugar (III) to give said preparation comprising said compound (I).

111. (New) The preparation according to claim 100, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

insulin is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

112. (New) The preparation according to claim 100, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

insulin and said sugar (III) are encapsulated in a pharmaceutical carrier, and said insulin is reacted with said sugar (III) to give said compound (I) in said pharmaceutical carrier.

113. (New) The preparation according to claim 100, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

insulin is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

114. (New) The preparation according to any one of claims 110-113, wherein said pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

115. (New) The preparation according to claim 101, wherein said compound (I)

is in a pharmaceutical carrier obtained by the following steps:

enkephalin is combined with a pharmaceutical carrier, to obtain an enkephalin-carrier composition, and said enkephalin-carrier composition is reacted with said sugar (III) to give said preparation comprising said compound (I).

116. (New) The preparation according to claim 101, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

enkephalin is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

117. (New) The preparation according to claim 101, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

enkephalin and said sugar (III) are encapsulated in a pharmaceutical carrier, and said enkephalin is reacted with said sugar (III) to give said compound (I) in said pharmaceutical carrier.

118. (New) The preparation according to claim 101, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

enkephalin is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

119. (New) The preparation according to any one of claims 115-118, wherein said pharmaceutical carrier is selected from the group consisting of liposome,

lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

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Examiner's Statement of Reasons for Allowance

10. The following is Examiner's statement of reasons for allowance:

The closest prior art are:

Sessler et al. (U.S. Patent 5,580,543);

Katsukiyo (JP-07-061999); and

Masashi et al (JP 9-263579).

The presently claimed invention comprising a pharmaceutical composition produced via reacting a peptide having a free amino group with lactose or sialyl lactose or compounds wherein lactose or sialyl lactose are chemically bound to a polymer among polyoxyethylene, polyglutamic acid, and polyvinylpyrrolidone via the hydroxyl group other than the hydroxyl group formed from the reducing aldehyde group of lactose or sialyllactose is not taught by any of the references cited *supra* either individually or in combination.

Thus, none of the art cited *supra* alone or in combination teach or reasonably suggest to obtain a pharmaceutical composition produced via reacting a peptide having a free amino group with lactose or sialyl lactose or compounds wherein lactose or sialyl lactose are either chemically bound to a polymer among those recited in the claimed invention, or lactose or sialyllactose are bound to said polymers according to the method recited in the claimed invention.